

T. Osypka
U.S. Serial No. 10/625,175
Page 9 of 13

REMARKS

Claims 1-47 are pending in the application. Claims 1-3, 8, 13, 14, 16, 17, 23, 26, 32, 33, 36, 44, and 46 have been amended by the present amendment. The amendments are fully supported by the application as originally filed.

Claims 1-4, 13, 14, 16, 17, 23, 24, 32, 33, 36, and 46 were rejected under 35 USC 112, second paragraph, as being indefinite. Specifically, regarding claims 1, 23, and 36, the Examiner inquired whether the bipolar cardiac lead contains more than one electrode. Claims 1, 23, and 36 recite "an electrode housing," which is capable of accommodating one or more electrodes. It is not believed necessary to amend claims 1, 23, and 36 to restrict the number of electrodes.

Regarding the rejection of claims 1, 23, and 36 because of the language "to affix the electrode housing to the cardiac tissue," the Examiner's recommendation has been adopted, and the claims have been amended to recite "for affixing the electrode housing to the cardiac tissue," thereby obviating the rejection.

Regarding the rejection of claim 1 because of the term "electrically active," claim 1 has been amended to recite a conductor coil extending through the elongated lead body, where the conductor coil is electrically connected to at least a connective portion of the electrode housing, and the helical fixation screw is electrically connected to the connective portion of the electrode housing. It is believed that the amendments to claim 1 obviate the rejection.

Regarding the rejection of claim 2 because of the terms "externally threaded plug" and "internally threaded collar," claim 2 has been amended to positively recite these terms, thereby obviating the rejection.

Regarding the rejection of claim 3 because of the term "self-sealing opening," claim 3 has been amended to positively recite this term, thereby obviating the rejection.

T. Osypka
U.S. Serial No. 10/625,175
Page 10 of 13

Regarding the rejection of claims 4 and 24 because of the term "scrowdriver tipped stylet," claims 3 and 23 have been amended to positively recite this term, thereby obviating the rejection.

Regarding the rejection of claims 13-14, 32-33, and 46 because of the terms "anode" and "cathode," these claims (and also claim 44) have been amended to recite the language "adapted to serve," as recommended by the Examiner.

Regarding the rejection of claims 16 and 17, these claims have been amended to recite "adapted to penetrate," as recommended by the Examiner. It is believed that all of the rejections under 35 USC 112, second paragraph, have been addressed and overcome.

Claims 1, 5, 6, 20, 36, and 37 were rejected under 35 USC 102(b) as being anticipated by U.S. Patent 4,299,239 to Weiss et al. (hereinafter "Weiss"). Claims 1, 20, 22, 23, and 31 were rejected under 35 USC 102(b) as being anticipated by U.S. Patent 5,531,780 to Vachon. Claims 1, 20, 22, 23, and 31 were rejected under 35 USC 102(b) as being anticipated by U.S. Patent 5,545,201 to Helland et al. ("Helland"). Claims 1, 2, 20, 22, 23, and 31 were rejected under 35 USC 102(e) as being anticipated by U.S. Patent 6,819,959 to Doan et al. (hereinafter "Doan"). The remaining claims were rejected on combinations of these references. All of the rejections are respectfully traversed.

As amended, independent claims 1, 23, and 36 each recite "an insulating tube positioned radially outside of the helical fixation screw in the electrode housing for eluting at least one drug." This amendment is supported by the specification as originally filed (see, e.g., page 13, line 9 to page 14, line 7; and FIGS. 4a-4b).

For example, referring to FIGS. 4a and 4b of the application, an insulating tube 38 is positioned radially outside of the helical fixation screw 32 within the electrode housing 14, and more specifically, between the helical fixation screw 32 and a ring electrode 28. The insulating tube 38 can be formed from a compound including an elastomeric material and a therapeutic

T. Osypka
U.S. Serial No. 10/625,175
Page 11 of 13

drug, where the drug can elute from the elastomer over time (see specification at page 13, lines 12-15).

Regarding the rejection of independent claims 1 and 36 over Weiss, the Weiss reference does not teach or suggest a bipolar cardiac lead or implantation kit including "an insulating tube positioned radially outside of the helical fixation screw in the electrode housing for eluting at least one drug."

Referring to FIG. 4A of Weiss, a screwdriver tool 70 is configured for insertion into an insertion tool 60 in order to affix a screw element 50 to a patient's heart H (see FIGS. 5A-5C; and column 6, lines 47-51 of Weiss).

However, Weiss does not teach or suggest an insulating tube positioned radially outside of the screw element 50 for eluting at least one drug. Weiss does not provide any drug-eluting device.

Moreover, in Weiss, the screw element 50 is not electrically connected to at least a portion of an electrode housing, as recited in claim 1. In Weiss, the screw element 50 is simply screwed into the heart wall, where a needle portion/probe 38 delivers "stimulus signals" (see column 4, lines 9-23; and column 5, lines 10-13). The screw element 50 is not provided for stimulating cardiac tissue, as recited in claims 1 and 23.

For at least the reasons discussed above, the Weiss reference does not anticipate or otherwise render obvious the Applicant's claimed invention.

Regarding the rejection of independent claims 1 and 23 over Vachon, the Vachon reference does not teach or suggest a bipolar cardiac lead or implantation kit including "an insulating tube positioned radially outside of the helical fixation screw in the electrode housing for eluting at least one drug."

T. Osypka
U.S. Serial No. 10/625,175
Page 12 of 13

In Vachon, a stylet 66 extends through a pacing lead 20, as shown in FIG. 2 (see column 4, lines 33-43). A therapeutic agent delivering dart 62 is provided inside of a fixation helix electrode 82 mounted on a base 55 (see column 5, lines 1-5), where the dart 62 is retained inside the helix 82 establishing a friction fit (see column 5, lines 23-29).

Vachon does not teach or suggest an insulating tube positioned "radially outside of the helical fixation screw," as recited in independent claims 1 and 23. In Vachon, the dart 62 is provided inside of the helix 82, which is necessary to establish a friction fit for permitting "the dart 62 to be driven into the myocardial tissue merely under the action of inner wire 68" (see column 5, lines 23-29).

Moreover, Vachon does not teach or suggest a helical fixation screw provided "along an axis extending generally perpendicular to the longitudinal axis of the lead body," as claimed. Instead, in Vachon, the helix 82 is driven parallel to the longitudinal axis of the lead body 22.

For at least the reasons discussed above, the Vachon reference does not anticipate or otherwise render obvious the Applicant's claimed invention.

Regarding the rejection of independent claims 1 and 23 over Helland, the Helland reference does not teach or suggest a bipolar cardiac lead or implantation kit including "an insulating tube positioned radially outside of the helical fixation screw in the electrode housing for eluting at least one drug."

In Helland, a helix 44 is advanceable to penetrate the myocardium of the heart (see column 2, lines 64-67). Helland does not teach or suggest an insulating tube for eluting at least one drug.

Moreover, Helland does not teach or suggest a helical fixation screw provided "along an axis extending generally perpendicular to the longitudinal axis of the lead body," as claimed. Instead, in Helland, the helix 44 is driven parallel to the longitudinal axis of the lead body 22.

T. Osypka
U.S. Serial No. 10/625,175
Page 13 of 13

For at least the reasons discussed above, the Helland reference does not anticipate or otherwise render obvious the Applicant's claimed invention.

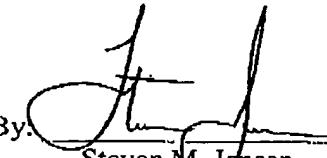
Regarding the rejection of independent claims 1 and 23 over Doan, the Doan reference does not teach or suggest a bipolar cardiac lead or implantation kit including "an insulating tube positioned radially outside of the helical fixation screw in the electrode housing for eluting at least one drug."

Moreover, Doan does not teach or suggest a helical fixation screw provided "along an axis extending generally perpendicular to the longitudinal axis of the lead body," as claimed. Instead, in Doan, a helix 104 is driven parallel to the longitudinal axis of the lead body 22.

For at least the reasons discussed above, the Doan reference does not anticipate or otherwise render obvious the Applicant's claimed invention.

It is believed that the claims are in condition for immediate allowance, which action is earnestly solicited.

Respectfully submitted,

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